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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

SANOFI-AVENTIS U.S. LLC AND REGENERON PHARMACEUTICALS, INC., Petitioners

v.

GENENTECH, INC. AND CITY OF HOPE Patent Owners

> Case IPR2015-01624 Patent 6,331,415

EXPERT DECLARATION OF JOHN FIDDES, PH.D.

IPR2016-00710 Genentech Exhibit 2139 cont. SANOFI v. GENENTECH IPR2015-01624 EXHIBIT 2019

Mylan/Merck v. Genentech

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		1.	What is the focus of the Bujard reference?	
		2.	Do the references to "multimers" and "one or more structural genes" in Bujard suggest the use of the co-expression of multiple, distinct eukaryotic genes of interest in a single host cell?	
		3.	Do the references to multiple "stop codons" in Bujard suggest the use of the strong promoter/terminator system for the expression of multiple, distinct genes in a single host cell? 72	
		4.	Does Bujard "at least suggest the coexpression of the heavy and light chains" of an immunoglobulin in a "single host cell," as the Board found?	
		5.	Does Bujard "teach away from the production of light chains in one culture and heavy chains in another, to be combined chemically at a stage after their harvest and isolation," as Dr. Foote argues?	
		6.	Does the statement in Bujard that the "proteins may be prepared as a single unit or as individual subunits and then joined	

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		together in appropriate ways" suggest in vivo assembly of a multimeric protein in a single host cell, as Dr. Foote argues?. 84		
	7.	Do you agree with the Board's finding that Bujard is "more specific and robust" than the Axel reference?		
Β.	Rigg	s & Itakura		
	1.	What is the focus of the Riggs & Itakura reference?		
	2.	Does the Riggs & Itakura reference address the "same problem" as Bujard and would the skilled artisan have had "good reason" to combine these two references in April 1983?		
	3.	Would inferences gleaned from Riggs & Itakura have provided the person of ordinary skill with the motivation to "selectively apply the teachings of Bujard to the specific production of immunoglobulins" by means of co-expressing both the heavy and light chain in a single host cell?		
	4.	Do you agree with Dr. Foote's opinion and the Board's preliminary finding that Bujard in combination with Riggs & Itakura renders the claimed invention of the Cabilly '415 patent obvious?		
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	3.	Would inferences gleaned from Southern have provided the person of ordinary skill with the motivation to "selectively apply the teachings of Bujard to the specific production of immunoglobulins" by means of co-expressing both the heavy and light chain in a single host cell?		

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